64. (New) A reagent for the detection of an antibody against HIV by means of an immunoassay comprising at least one antigen mixture of claim 59.

E' cont'd.

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REMARKS

In view of the amendments and cancellation above, claims 44-64 are now pending.

Support for claim 44 may be found throughout the specification, including on page 3, 4th paragraph, and on page 4, 1st and 2nd paragraphs. Support for claim 45 may be found throughout the specification, including on page 9, 2nd paragraph. Support for claim 46 may be found throughout the specification, including on page 7, 1st paragraph. Support for claims 47, 48, and 54 may be found throughout the specification, including on page 5, 2nd and 3rd paragraphs. Support for claims 49 and 53 may be found throughout the specification, including on page 10, last paragraph. Support for claim 50 may be found throughout the specification, including on pages 12 and 13, last paragraph and 2nd paragraph, respectively. Support for claims 51 and 52 may be found throughout the specification, including on page 10, 1st paragraph. Support for claim 55 may be found throughout the specification, including on page pg. 9, 1st paragraph. Support for claim 56 may be found throughout the specification, including on page 11, 2nd and 3rd paragraphs. Support for claim 57 may be found throughout the specification, including on page 13, 2nd paragraph. Support for claim 58 may be found throughout the specification, including on page 11, 4th paragraph. Support for claims 59 and 60-63 may be found throughout the specification, including on page 12, 1st and 2nd

paragraphs, respectively. Support for claim 64 may be found throughout the specification, including on page 17, 3rd paragraph. No new matter has been added.

Sequence Listing Requirement:

In response to the Examiner's request, Applicants herein provide the Sequence Listing in a written and electronic form, along with a Statement certifying that the written form of the Sequence Listing does not go beyond the disclosure of the specification and that the electronic form of the Sequence Listing is identical to the written form.

Rejection under 35 USC § 112, second paragraph:

The Examiner rejected claims 34-43 under 35 USC § 112, second paragraph, for being indefinite and for failing to point out and distinctly claim the subject matter which Applicants regard as their invention.

In paragraph three of the Examiner's rejection, claims 34, 39, and 41 were rejected as unclear because the antigen epitope region was not defined in the claims. Also, according to the Examiner, Applicants did not clearly define intended epitopes and/or antigens of the present invention. This ground of rejection is moot in view of the cancellation of claims 34, 39, and 41.

Moreover, this rejection should not be applied to new method claims 44-54 as these claims are not directed to the antigens themselves, but rather to an immunoassay method. Specifically, claims 44-54 are directed to an immunoassay method for detection of an antibody against HIV by contacting the sample with at least one antigen mixture. The sample can be contacted with a first antigen mixture, which includes a first

antigen derived from an epitope region II of gp 41, including amino acids 518-533 thereof, of an HIV1-subtype D isolate, and a second antigen derived from an epitope region II of gp41 of a different HIV1 subtype of the M group. In addition, the sample can also be contacted with a second antigen mixture, which includes a third antigen derived from an epitope region I of gp 41, including amino acids 551-565, of an HIV1-subtype E isolate, and a fourth antigen derived from an epitope region I of gp41 of a different HIV1 subtype of the M group. The recitation of the antigens suitable for this method claims is entirely clear from the language of these claims when read in light of the specification, including several examples.

In addition, the Examiner's § 112, second paragraph, rejection should not be applied to new claims 55-64, as these claims are directed to the mixtures of antigens. The language in claims 55-64 has been amended to clearly define these antigen mixtures.

In paragraph four of the Examiner's rejection, claim 43 was rejected for being vague and indefinite as the metes and bounds of "analyte" are not defined as the claim uses "comprising" and fails to define whether the antigen contains "a ten amino acid sequence" or "a ten amino acid sequence" is only a part of an antigen structure. This ground of rejection is moot in view of the cancellation of claim 43.

Moreover, this rejection should not be applied to new claims 51-53, 56, 61, and 63. New claims 52, 61, and 51, 56 clearly define "the first antigen" as having a minimum length of either seven or ten amino acids, respectively. New claims 53 and 63 define "the third antigen" as having a minimum length of six amino acids.

In view of the amendments and remarks above, all of the newly presented claims meet the requirements of 35 U.S.C. § 112, second paragraph.

Rejection under 35 USC § 102(e):

Claim 43 has been rejected under 35 USC § 102(e) as being anticipated by De Leys *et al.* (US Patent No. 5,891,640 A). The Examiner asserts that the De Leys *et al.* discloses a method for detecting an antibody against HIV-1 by contacting the sample with an antigen of HIV gp41 antigen sequence (SEQ ID NO. 2 in the reference), which is 21 amino acids long and comprises the 10 amino acid sequence of Applicant's SEQ ID NO. 36. Applicants submit that this ground of rejection is moot in view of the cancellation of claim 43.

Moreover, this rejection should not be applied to newly presented claims 44-54, as the antigens recited in these claims are different than the antigens taught by De Leys *et al.* reference. Contrary to the Examiner's assertion, the SEQ ID NO. 2, as taught by De Leys *et al.*, does not include the same ten amino acids sequence as Applicants' SEQ ID NO. 36. This is shown in the following table:

De Leys SEQ ID NO. 2	I	W	G	C	S	G	K	L	I	C	T	T	A	V	P	W	N	A	S
Applicant's SEQ ID NO. 36				C	S	G	R	**H**	I	C	T	T	N						

More specifically, De Leys *et al.* reference does not teach a characteristic Histidine (H) (bolded), which is present in the sequences in the loop between the two Cysteines (C) according to the present invention. Rather, the sequence disclosed in De Leys *et al.*

incorporates Leucine (L) rendering the sequence structurally and functionally different than Applicant's sequences.

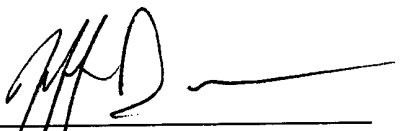
Also, a § 102(e) rejection would be improper because the applied reference fails to teach each and every element of new claim 44. In particular, the reference does not teach or suggest Applicants' immunoassay method for detection of an antibody against HIV with an antigen mixture that combines a first antigen derived from an epitope region II of gp 41, including amino acids 518-533 thereof, of an HIV1-subtype D isolate, and a second antigen derived from an epitope region II of gp41 of a different HIV1 subtype of the M group. Nor does De Leys *et al.* reference teach contacting the sample with an antigen mixture that combines a third antigen derived from an epitope region I of gp 41, including amino acids 551-565, of an HIV1-subtype E isolate, and a fourth antigen derived from an epitope region I of gp41 of a different HIV1 subtype of the M group.

Consequently, for at least these reasons, De Leys *et al.* cannot anticipate new claim 44 or any of the claims that depend therefrom.

CONCLUSION

The Applicants respectfully submit that new claims 44-64 are patentable and the present application is in condition for allowance. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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